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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,530	10/24/2000	Lars Wahlberg	19313-004 (NS-4)	4889
35437	7590	11/04/2003	EXAMINER	
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO 666 THIRD AVENUE NEW YORK, NY 10017			NICHOLS, CHRISTOPHER J	
		ART UNIT	PAPER NUMBER	
		1647		

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/696,530	WAHLBERG ET AL.	
	Examiner Christopher Nichols, Ph.D.	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 August 2003.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15, 17-23 and 42-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 42 is/are allowed.
- 6) Claim(s) 1-15, 17-23 and 43-56 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 August 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                     | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The Response/Amendment filed 13 August 2003 has been received and entered in full. Claims 1, 3, 22, and 42 have been amended. Claims 16 and 24-41 have been cancelled. Claims 1-15, 17-23, and 42-56 are under examination.

### ***Withdrawn Objections And/Or Rejections***

2. The Objection to the Oath/Declaration as set forth at pp. 4 ¶12 in the previous Office Action (13 May 2003) is *withdrawn* in view of Applicant's submission of a copy of the Oath/Declaration signed by Inventor Kenneth Campbell.
3. The Objection to the Drawings as set forth at pp. 4 ¶13 in the previous Office Action (13 May 2003) is *withdrawn* in view of Applicant's amendments (13 August 2003).
4. The Objection to claim 16 as set forth at pp. 7 ¶22 in the previous Office Action (13 May 2003) is *withdrawn* in view of Applicant's cancellation of said claim (13 August 2003).
5. The Rejection of claim 42 under 35 U.S.C. §102(b) as set forth at pp. 10 ¶29 in the previous Office Action (13 May 2003) is *withdrawn* in view of Applicant's amendment (13 August 2003).
6. The Rejection of claims 1-21 and 50-56 under 35 U.S.C. §112 ¶1 as set forth at pp. 4-7 ¶14-21 in the previous Office Action (13 May 2003) is *withdrawn in part* in view of Applicant's amendments (13 August 2003).

7. The Rejection of claims 22, 23, and 43-49 under 35 U.S.C. §112 ¶1 as set forth at pp. 7-9 ¶23-28 in the previous Office Action (13 May 2003) is *withdrawn in part* in view of Applicant's amendments (13 August 2003).

***Maintained Objections And/Or Rejections***

8. The rejection of claims **1-15, 17-21.** and **50-56** under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *an isolated culture of neuronal cells wherein the proliferation-inducing growth factor is as instantly claimed wherein the neuronal cells are GFAP<sup>+</sup> and nestin<sup>+</sup>, and further, wherein the neuronal cells are immunoreactive with striatal neuronal markers wherein said striatal neuronal markers are DLX1 and/or MEIS2 but said neuronal cells are NOT immunoreactive with cortical neuronal markers wherein said cortical neuronal marker is PAX6, does not reasonably provide enablement for any other neuronal cells.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims for the reasons as set forth in at pp. 3-6 ¶8-14 of the previous Office Action (15 January 2003) and as set forth at pp. 4-7 ¶14-21 in the previous Office Action (13 May 2003) is *maintained in part.*

9. The rejection of claims **22, 23,** and **43-49** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a method of producing a neuronal cell in vitro wherein the proliferation-inducing is as instantly claimed, wherein the neuronal cells are GFAP<sup>+</sup> and nestin<sup>+</sup>, and further, wherein the neuronal cells are immunoreactive with striatal neuronal markers wherein said striatal neuronal markers are DLX1 and/or MEIS2 but*

*said neuronal cells are NOT immunoreactive with cortical neuronal markers wherein said cortical neuronal marker is PAX6, does not reasonably provide enablement for use of other neuronal cells.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for the reasons as set forth at pp. 4-7 ¶¶14-21 in the previous Office Action (13 May 2003) is *maintained in part*.

10. It is noted that Applicant traversed both the rejection of claims 1-21 and 50-56 with the traversal of claims 22, 23, and 43-49 in the same response (pp. 9-12). The Examiner acknowledges the combination of the response and the response filed 13 August 2003 is considered complete by the Examiner pursuant to 37 C.F.R. §1.111.

11. Applicant traverses this rejection for following three reasons: (a) the growth factors as now included in the claims are enabled, (b) Kalyani *et al.* (1998) is not applicable to the presently claimed GFAP<sup>+</sup> cells, and (c) US 6040180 is indicative of the state of the art at the time it was filed 1996 and is not applicable to the presently claimed GFAP<sup>+</sup> cells. Applicant's arguments have been taken into consideration and are not found persuasive for the following two reasons.

12. On "(a)", the Examiner has *withdrawn* the rejection under 35 U.S.C. §112 ¶1 on these grounds.

13. On "(b)", Kalyani *et al.* (1998) is relevant as it teaches the obstacles and difficulty in using stem cells pursuant to MPEP §2164.03. The fact that Kalyani *et al.* (1998) does not teach the instantly claimed GFAP<sup>+</sup> cells is relevant in so far as it is not a valid 35 U.S.C. §102 reference.

14. On "(c)", in response to applicant's argument based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977). US 6040180 teaches the obstacles and unpredictability of stem cells. US 6040180 remains relevant as it presents obstacles and difficulties which must be overcome to successfully practice the instant invention despite the lack of specifically reciting the presently claimed GFAP<sup>+</sup> cells (and as such does not qualify it as a reference under 35 U.S.C. §102).

15. The rejection of claims 1-15, 17-21 and 50-56 as well as the rejection of claims 22, 23, and 43-49 is hereby maintained.

### *Summary*

16. Claim 42 is free of the prior art.

17. Claims 1-15, 17-23, and 43-56 are hereby rejected.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
October 27, 2003

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER